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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/800,463	03/08/2001	Nadia Avalle	P66420US0	4904

7590 08/12/2003

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EXAMINER

WANG, SHENGJUN

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 08/12/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/800,463

Applicant(s)

AVALLE, NADIA

Examiner

Shengjun Wang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 6-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,6-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 27, 2003 has been entered.

Claim Rejections 35 U.S.C. 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by Gustafsson et al (of record).

4. Gustafsson et al. teaches a sustained release coated microparticles, wherein the core material for the microparticles is starch (col. 4, lines 44-45). Starch is considered an excipient (see page 4, lines 10-12 herein in the specification), and the coating polymers are copolymers from alpha hydroxy acids, specifically, polylactide. The amount of polymer is about 45% and the amount of core particles is about 55%. (see, col. 10, the example 6). Note the intended use of the particles "cosmetic" is not render the claimed particle any patentable weight since it is well settled that the "intended use" of a product or composition will not further limit claims drawn to

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a product or composition. See, e.g., In re Hack 114 USPQ 161. Further, the functional description of the hydroxy acid polymer (degrade and release hydroxy acid) is not seen to further limit the claims since the properties of the polymer cannot be separated from the polymer.

Claim Rejections 35 U.S.C. 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-3 and 6-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gustafsson et al. (of record).

7. Gustafsson et al. teaches a sustained release coated microparticles (see the abstract). The preferred core material for the microparticles is starch (col. 4, lines 44-45). Starch is considered an excipient (see page 4, lines 10-12 herein in the specification). Preferred coating polymers are polyester or copolymers from alpha hydroxy acids, particularly, polylactide. Various agents may be incorporated into the coating, including ascorbic acid (see, col. 4, lines 44-63). The coating may be realized by preparing a polymer solution and applied to the core particles. The drying can be accomplished by any appropriate means, such as spray drying. Ethyl acetate is used in the procedure for applying the coating to the particles (col. 10, lines 15-45). The amount of the polymer coating materials range from 5 to 100 percent by weight relative to the core weight, i.e., 2.5 to 50 % of the total particle weight (see claim 22).

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8. The reference does not teach expressly the particular percentage of each component, or the particular process of coating.

9. However Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to make coated particulates with the particular percentage of each components, or with the particular process herein claimed because such percentage or process are generally disclosed by the reference. It is well settled in the patent law that it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Note the intended use of the particles “cosmetic” is not render the claimed particle any patentable weight since it is well settled that the “intended use” of a product or composition will not further limit claims drawn to a product or composition. See, e.g., In re Hack 114 USPQ 161. Further, the functional description of the hydroxy acid polymer (degrade and release hydroxy acid) is not seen to further limit the claims since the properties of the polymer cannot be separated from the polymer.

Response to the Arguments

Applicants’ amendments and remarks submitted April 21, 2003 have been fully considered. In view of the amendments, the rejections under 35 USC 112, and the rejections over Elwakil set forth in the prior office action have not been applied herein. However, the amendments and arguments are not persuasive with respect to Gustafsson reference for reasons discussed above. Note the claimed invention is directed to alpha hydroxy acid polymer coated particles, wherein the core materials read on the core material employed by Gustafsson et al. The intended use and the functional limitation do not distinct the claimed subject matter from those

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disclosed by cited reference. Absent material limitation, the claims are properly rejected over Gustafsson

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Patent Examiner

 **SHENGJUN WANG**
PATENT EXAMINER

Shengjun Wang

August 5, 2003